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|-----------------------------------------------------------------------|-------------|----------------------|---------------------|------------------|
| 10/594,791                                                            | 07/18/2007  | Robert Charles Rees  | 42133-200861        | 9495             |
| 23643                                                                 | 7590        | 08/04/2009           | EXAMINER            |                  |
| BARNES & THORNBURG LLP<br>11 SOUTH MERIDIAN<br>INDIANAPOLIS, IN 46204 |             |                      |                     | DUFFY, BRADLEY   |
| ART UNIT                                                              |             | PAPER NUMBER         |                     |                  |
|                                                                       |             | 1643                 |                     |                  |
| NOTIFICATION DATE                                                     |             |                      | DELIVERY MODE       |                  |
| 08/04/2009                                                            |             |                      | ELECTRONIC          |                  |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

indocket@btlaw.com

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 10/594,791             | REES ET AL.         |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | BRADLEY DUFFY          | 1643                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 25 March 2009.  
 2a) This action is **FINAL**.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-8, 10, 13-25, 27-31, 34 and 35 is/are pending in the application.  
 4a) Of the above claim(s) 1-6, 10, 13-25, 28-30, 34 and 35 is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 7, 8, 27 and 31 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on 29 September 2006 is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

|                                                                                                             |                                                                   |
|-------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                        | Paper No(s)/Mail Date. _____ .                                    |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____. | 5) <input type="checkbox"/> Notice of Informal Patent Application |
|                                                                                                             | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

1. The amendment filed March 25, 2009, is acknowledged and has been entered. Claims 1, 3, 4, 7, 8, 10, 15, 16, 21-23, 28, 29 and 31 have been amended. Claims 9 and 26 have been canceled. Claims 34 and 35 have been newly added.
2. Claims 1-8, 10, 13-25, 27-31, 34 and 35 are pending in the application.
3. Claims 1-6, 10, 13-25, 28-30, 34 and 35 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant elected with traverse in the reply filed March 12, 2008.
4. Claims 7, 8, 27 and 31 are under examination.

### ***Election/Restrictions***

5. At page 8 of the response Applicant has reiterated their traversal of the restriction and election requirement set forth in the Office action mailed December 12, 2007.

In response, for the reasons of record as set forth in the previous office action the requirement was previously made FINAL.

Notably, in light of the art rejections set forth in the previous action that teach an isolated polypeptide comprising the amino acid sequence of SEQ ID NO:1, it is apparent that the originally claimed inventions were not linked by a special technical feature.

Furthermore, it is noted that claim 28 has been amended and claims 34 and 35 have been newly added, so as to be drawn to the non-elected invention of group III. For this reason, these claims have been withdrawn from further consideration.

***Grounds of Objection and Rejection Withdrawn***

6. Unless specifically reiterated below, Applicant's amendment and/or arguments filed December 9, 2008, or March 25, 2009, have obviated or rendered moot the grounds of objection and rejection set forth in the previous Office action mailed June 11, 2008.

***Claim Rejections - 35 USC § 112***

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. The rejection of claims 7, 27 and 31 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, is maintained.

In this case, claims 7, 27 and 31 remain indefinite and have been amended to recite "conditions of high stringency" instead of "specifically hybridises".

At page 10 of the amendment filed December 9, 2008, Applicant has traversed this ground of rejection arguing that the specification provides stringent conditions at page 5, lines 17-18, which recites, "[t]ypical conditions for high stringency include 0.1 x SET, 0.1% SDS at 68 °C for 20 minutes."

In response, as set forth in the previous office action, this is not a limiting definition of stringent conditions, it is merely exemplary. In this case, the high stringency hybridization conditions will vary, such that those conditions would allow *different* oligonucleotides to hybridize or not depending on the conditions used. Notably, adding the relative term "high" does not obviate the issue because once again, the specification presents a merely exemplary set of "high stringency conditions" and limitations from the specification are not read into the claims. Therefore, the metes and bounds of the subject matter that Applicant regards as the invention will vary;

accordingly, these claims fail to delineate the metes and bounds of the subject matter that Applicant regards as the invention with the requisite particularity and clarity.

Accordingly, after careful and complete consideration of Applicant's amendment, it is maintained that these claims fail to delineate the metes and bounds of the subject matter that Applicant regards as the invention with the requisite clarity and particularity to permit the skilled artisan to know or determine infringing subject matter.

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. The rejection of claims 7-8, 27 and 31 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, is maintained. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This is a "written description" rejection.

At page 11 of the amendment filed December 9, 2008, Applicant has traversed this ground of rejection and appears to be arguing that skilled artisans would know which nucleic acid molecules would hybridize under conditions of "high stringency" and that the polypeptides reciting percent identities as set forth in claim 7 are sufficient to provide adequate written description of the claimed T128 polypeptides based on the USPTO Written Description Training Guidelines.

Again, the considerations that are made in determining whether a claimed invention is supported by an adequate written description are outlined by the published Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, para. 1, "Written Description" Requirement (Federal Register; Vol. 66, No. 4, January 5, 2001; hereafter "Guidelines"). A copy of this publication can be viewed or acquired on the

Internet at the following address: <http://www.gpoaccess.gov/>.

In response to Applicant's argument that the skilled artisan would know which nucleic acid molecules will hybridize under conditions of "high stringency", since the claims do not define any conditions of stringency, this argument is not found persuasive. Once again, limitations from the specification will not be read into the claims.

Secondly, in response to Applicant's argument that the claimed genera of "T128 polypeptides" which include polypeptides identified only by percent identify and "pharmaceutically effective fragments thereof" as encompassed by the claims, are adequately described based on USPTO Written Description Training Guidelines, it is noted the Federal Circuit has commented that each case involving the issue of written description, "must be decided on its own facts. Thus, the precedential value of cases in this area is extremely limited." *Vas-Cath*, 935 F.2d at 1562 (quoting *In re Driscoll*, 562 F.2d 1245, 1250 (C.C.P.A. 1977)). See *Noelle v. Lederman*, 69 USPQ2d 1508 (CAFC 2004).

Notably, in this case, as set forth in the previous office action the genus of "T128" polypeptides encompassed by the claims is highly structurally and functionally diverse and these polypeptides do not share any particularly identifying (i.e., substantial) structural feature, which correlates with any one particularly identifying functional feature that is also shared by many, if not all, of these polypeptides which would allow one of skill in the art to immediately envision, recognize or distinguish at least most of its members from other proteins.

For example, as set forth at page 7 of the specification, the genus of polypeptides which are identified by percent identity alone or are fragments thereof as encompassed by the claims includes "polypeptide analogues, fragments or derivatives of antigenic polypeptides which differ from naturally-occurring forms in terms of the identity of location of one or more amino acid residues (deletion analogues containing less than all of the residues specified for the protein, substitution analogues wherein one or more amino acid residues are added to a terminal or medial portion of the polypeptides) and **which share some or all properties of the naturally-occurring**

**forms**<sup>1</sup>. Preferably such polypeptides comprise between 1 and 20, preferably 1 and 10 amino acid deletions or substitutions.

Notably, in this case, the specification does not identify any regions or domains in any “T128 polypeptide” which are required for a “T128 polypeptide” to have **some or all properties of the naturally-occurring forms** and does not identify any fragments of any “T128 polypeptide” that would be “pharmaceutically effective” and therefore it is apparent that one of skill in the art would not be able to immediately envision, recognize or predict the structure and/or function of the “polypeptides” or “fragments thereof” which are encompassed by the claims.

For example, as set forth in the previous office action, it is well-established in the art that there is a high degree of unpredictability in determining the three-dimensional structure and function of a given protein *a priori* given its amino acid sequence.

As evidenced by Jones (Pharmacogenomics Journal, 1:126-134, 2001, of record), protein structure “prediction models are still not capable of producing accurate models in the vast majority of cases” (page 133, 3<sup>rd</sup> paragraph). Furthermore, Tosatto et al state, “the link between structure and function is still an open question and a matter of debate” (Current Pharmaceutical Design, 12:2067-2086, 2006, page 2075, 1<sup>st</sup> new paragraph). Therefore, even if the skilled artisan were able to submit a complete list of all the possible proteins, fragments and protein derivatives which fall within the scope of the claims, the skilled artisan would not be able to immediately envision, recognize or predict the three-dimensional structure and function of a given protein *a priori* based on this amino acid sequence in order to identify the “T218 polypeptides” and “pharmaceutically effective fragments” thereof which are encompassed by the claims.

Accordingly, after careful and complete consideration of Applicant's arguments, for these reasons and for the reasons set forth in the previous office action, the specification as filed does not adequately describe the polypeptides and fragments thereof to which the claims are directed and this rejection is maintained.

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<sup>1</sup> Emphasis added

11. The rejection of claims 7-8, 27 and 31 under 35 U.S.C. 112, first paragraph, because the specification, **while being enabling for making and using** an isolated polypeptide consisting of the amino acid sequence of SEQ ID NO:1, **and while being enabling for making and using** any polypeptides encompassed by the claims, which have been described by the prior art, **does not reasonably provide enablement for making and using** the full scope of the claimed polypeptides and fragments thereof, is maintained. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

MPEP § 2164.01 states:

The standard for determining whether the specification meets the enablement requirement was cast in the Supreme Court decision of *Mineral Separation v. Hyde*, 242 U.S. 261, 270 (1916) which postured the question: is the experimentation needed to practice the invention undue or unreasonable? That standard is still the one to be applied. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). Accordingly, even though the statute does not use the term "undue experimentation," it has been interpreted to require that the claimed invention be enabled so that any person skilled in the art can make and use the invention without undue experimentation. *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988).

Starting at page 12 of the amendment filed December 9, 2008, Applicant has traversed this ground of rejection.

Applicant's arguments have been carefully considered but not found persuasive for the following reasons:

In the traversal, Applicant has reiterated that that skilled artisans would know which nucleic acid molecules would hybridize under conditions of "high stringency" and that the polypeptides reciting percent identities as set forth in claim 7 are sufficient structural features to define the claimed T128 polypeptides based on the USPTO Written Description Training Guidelines.

In response, this argument is not persuasive because Applicant does not set forth any argument that one of skill in the art could **make and use** the recited polypeptides and fragments thereof without undue and unreasonable experimentation.

As set forth in the previous action, because it is well-established in the art that there is a high degree of unpredictability in determining the function of a given protein based on its amino acid sequence alone, as evidenced by Jones and Tosatto et al (supra), one of skill in the art would need specific guidance to enable them to make polypeptides or fragments that are functionally equivalent to the polypeptide consisting of the amino acid sequence of SEQ ID NO:1. Furthermore, one of skill in the art would be subject to undue and unreasonable experimentation to use the full scope of the claimed fragments as they would need to identify uses for the polypeptides or fragments encompassed by the claims which are not functionally equivalent to the polypeptide consisting of the amino acid sequence of SEQ ID NO: 1.

Secondly, Applicant presents arguments that the claimed kit of claim 28 is enabled.

In response, as set forth in the above Election/Restrictions section, the kit claimed in claim 28, which was previously drawn to the elected invention, has been amended to only read on a non-elected invention and has been withdrawn from further consideration.

Accordingly, the merits of Applicant's arguments pertaining to the kit of claim 28 are moot and have not been considered.

Finally, Applicant appears to argue that the claimed immunogenic compositions, which the specification sets forth at page 1 are to be used in adoptive immunity strategies targeting cancer, i.e., making people immune from developing cancer, comprising a polypeptide or pharmaceutically effective fragment thereof of the invention as encompassed by claim 7 are enabled because the ultimate success rates for vanquishing a particular type of cancer are not relevant to enablement of Applicant's claims and that Applicant's need not demonstrate that the claimed invention treats cancer in the clinic if there is a reasonable correlation between the activity and the asserted use.

In response, these arguments are not found persuasive, because as a first point, as set forth above, the immunogenic compositions continue to encompass T128

polypeptides or fragments thereof which one of skill in the art could not reasonably **make and use** without undue and unreasonable experimentation.

Secondly, while the Examiner agrees that Applicant's need not demonstrate that the claimed invention treats cancer in the clinic if there is a reasonable correlation between the activity and the asserted use, in this case there is no reasonable correlation submitted in the specification as filed that any immunogenic compositions comprising a T128 polypeptides or fragments thereof could treat or prevent any cancer. In this case, the specification only presents evidence that a species of T128 transcript is overexpressed in gastric and kidney cancers as compared to corresponding normal tissues (see Figure 3), which does not provide a reasonable correlation that a genus of T128 polypeptides and fragments thereof can be used to prevent or treat cancer for the reasons set forth in the previous office action without undue and unreasonable experimentation.

In this case, as set forth in the previous office action, based on the unpredictable state of the art in using polypeptides or fragments thereof to induce tumor immunity or treat cancer and the insufficient evidence or nexus presented in the specification that such polypeptides or fragments thereof induce tumor immunity or treat cancer which is needed to provide a reasonably enabling correlation, it is maintained that one of skill in the art would be subject to undue and unreasonable experimentation to use the claimed immunogenic compositions.

In conclusion, upon careful and full consideration of Applicant's response and arguments and the factors used to determine whether undue experimentation is required, in accordance with the Federal Circuit decision of *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988), the amount of guidance, direction, and exemplification disclosed in the specification, as filed, is not deemed sufficient to have enabled the skilled artisan to use the claimed invention at the time the application was filed without undue and/or unreasonable experimentation, and this rejection is being maintained.

***Claim Rejections - 35 USC § 102***

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. The rejection of claims 7-8, 27 and 31 under 35 U.S.C. 102(b) as being anticipated by US Patent Application Publication No. 2003/0092616 A1 (Matsuda et al, 2003, of record), is maintained.

Starting at page 15 of the amendment filed December 9, 2008, Applicant has traversed this ground of rejection.

Applicant's arguments have been carefully considered but are not found persuasive for the following reasons:

In the traversal Applicant has argued that Matsuda et al do not teach a polypeptide comprising SEQ ID NO:1 attached to a carrier protein because the interpretation of the term "carrier protein", as set forth in claim 27 is incorrect and does not comport with that term as viewed from the advantage point of the person of ordinary skill in the art and that the specification provides a non-limiting example of a carrier protein used to enhance immunogenicity, i.e., tetanus toxin.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., carrier protein used to enhance immunogenicity) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). In this case, Applicant has provided no evidence that one of skill in the art would view the term "carrier protein" to be limited to a carrier protein used to enhance immunogenicity, and as acknowledged by Applicant, the

specification only provides a non-limiting example of a “carrier protein”. Accordingly, Applicant has not provided a showing or made an amendment which distinguishes the subject matter of claim 27 from the prior art of US 20030092616 A1.

Secondly, it is noted that only claim 27 recites the limitation attached to a carrier protein. The other claims are broadly drawn to any polypeptide comprising the amino acid sequence of SEQ ID NO:1 since there is no clear indication in the specification as to what are the basic characteristics of a polypeptide consisting essentially of the amino acid sequence of SEQ ID NO:1 (see MPEP 2111.03). As set forth in the previous action, US 20030092616 A1 teaches isolated polypeptides that comprise the instantly claimed amino acid sequence of SEQ ID NO:1 and said polypeptides fused to other polypeptides, such as GST, and compositions thereof (see e.g., SEQ ID NO:74 and pages 2, 4 and 12).

Accordingly, after careful and complete consideration of Applicant's response and arguments, it is maintained that US 20030092616 A1 teaches products which are materially and structurally indistinguishable from the claimed products and that US 20030092616 A1 anticipates the claimed invention.

14. The rejection of claims 7-8, 27 and 31 under 35 U.S.C. 102(b) as being anticipated by WO 00/58473 A2 (Shimkets et al, 2000, of record), is maintained.

Starting at page 15 of the amendment filed December 9, 2008, Applicant has traversed this ground of rejection.

Applicant's arguments have been carefully considered but are not found persuasive for the following reasons:

In the traversal Applicant has presented the same argument set forth above relating to the interpretation of the term “carrier protein”.

In response, for the reasons set forth in the above Matsuda et al rejection this argument is not found persuasive.

In this case, as set forth in the previous action, WO 00/58473 A2 teaches isolated polypeptides that comprise the instantly claimed amino acid sequence of SEQ

ID NO:1 and said polypeptides fused to other polypeptides, such as GST or a signal sequence, and compositions thereof (see e.g., pages 2, 31 and SEQ ID NO:4798).

Accordingly, after careful and complete consideration of Applicant's response and arguments, it is maintained that WO 00/58473 A2 teaches products which are materially and structurally indistinguishable from the claimed products and that WO 00/58473 A2 anticipates the claimed invention.

### ***New Grounds of Rejection***

#### ***Claim Rejections - 35 USC § 112***

15. Claims 7, 27 and 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(i) In this case, the claims are indefinite because claim 7 has been amended to recite:

An isolated protein polypeptide consisting essentially of ***an amino acid sequence*** selected from the group consisting of:

- (a) T128 ***polypeptide*** (SEQ ID NO: 1);
- (b) a ***polypeptide*** with at least 90% sequence identity to SEQ ID NO: 1;
- (c) a ***polypeptide*** encoded by the nucleic acid sequence between nucleic acid residues 642 and 1688 of SEQ ID NO: 2;
- (d) a ***polypeptide*** encoded by a nucleic acid molecule with at least 95% sequence identity to the nucleic acid sequence between nucleic acid residues 642 and 1688 of SEQ ID NO: 2;
- (e) a ***polypeptide*** encoded by a nucleic acid molecule, the complementary strand of which hybridizes under conditions of high stringency to the nucleic acid molecule in (c) or (d) or the nucleic acid molecule encoding the polypeptide in (a) or (b).

Notably, the claim recites selecting ***an amino acid sequence*** from a Markush group, but the options recited for selection are ***polypeptides*** and not amino acid sequences *per se*. Therefore, the members of the Markush group lack proper

antecedent basis and the amino acid sequences that should be selected from is unclear. For example, is noted that after reciting “T128 *polypeptide*” that SEQ ID NO: 1 occurs in parenthesis. As such, it is submitted that it is unclear if this parenthetical reference is meant to further limit the claim to the amino acid sequence of SEQ ID NO:1, or if the reference is merely exemplary of a T128 *polypeptide*. Therefore the claims fail to delineate the metes and bounds of the subject matter that Applicant regards as the invention with the requisite clarity and particularity to permit the skilled artisan to know or determine infringing subject matter.

(ii) In this case, the claims are also indefinite because claim 7 has been amended to recite:

(e) a *polypeptide encoded by a nucleic acid molecule, the complementary strand of which* hybridizes under conditions of high stringency to the nucleic acid molecule in (c) or (d) or the nucleic acid molecule encoding the polypeptide in (a) or (b).

This recitation renders the claims indefinite because *nucleic acid molecules* can be single or double stranded and therefore *nucleic acid molecules* can have *one or two complementary strands*, and it is unclear which complementary strand is to be considered *the complementary strand* recited in the claim. Notably, each stand of a nucleic acid molecule would encode a different set of polypeptides, so without knowing which complementary strand is to be considered *the complementary strand*, the scope of the claims cannot be unambiguously construed. Therefore the claims fail to delineate the metes and bounds of the subject matter that Applicant regards as the invention with the requisite clarity and particularity to permit the skilled artisan to know or determine infringing subject matter.

For these reasons, it is submitted that these claims fail to delineate the metes and bounds of the subject matter that Applicant regards as the invention with the requisite clarity and particularity to permit the skilled artisan to know or determine infringing subject matter.

***Conclusion***

16. No claims are allowed.
17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brad Duffy whose telephone number is (571) 272-9935. The examiner can normally be reached on Monday through Friday 7:00 AM to 4:30 PM, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Respectfully,  
Brad Duffy  
571-272-9935

/Stephen L. Rawlings/  
Primary Examiner, Art Unit 1643

/bd/  
Examiner, Art Unit 1643  
July 28, 2009



